K132480

FEB 2 4 2014

AIR-FLOW handy 3.0 PERIO
Special 510(k) Premarket Notification 510(k) Summary
(per 21 CFR 807.92(c))

1. SPONSOR/MANUFACTURER

E.M.S. ELECTRO MEDICAL SYSTEMS S.A.
Ch. de la Vuarpillière 31
CH - 1260 Nyon
Switzerland

Contact Person: Suzanne Fassio-Hardy
Telephone: +41 (0)22 994 47 00

Date Prepared: August 28, 2013

2. DEVICE NAME:

Proprietary Name:	AIR-FLOW handy 3.0 PERIO
Common/Usual Name:	Dental handpiece
Classification Name:	Dental handpiece and accessories

3. PREDICATE DEVICE

- E.M.S. ELECTRO MEDICAL SYSTEMS S.A., AIR-FLOW handy PERIO (K082791)

4. DEVICE DESCRIPTION

The proposed AIR-FLOW handy 3.0 PERIO is a modification of the AIR-FLOW handy PERIO Dental Handpiece previously cleared under K092289. This device modification has been submitted as a Special 510(k) Premarket Notification because the indications for use for the proposed AIR-FLOW handy 3.0 PERIO are identical to the parent AIR-FLOW handy PERIO. The fundamental technology and design of the proposed AIR-FLOW handy 3.0 PERIO are essentially identical to the AIR-FLOW handy PERIO dental handpiece.

Both the proposed AIR-FLOW handy 3.0 PERIO and the predicate AIR-FLOW handy PERIO connect to a standard turbine connection on a dental operative unit and deliver a mixture of water, air, and dental powder to a treatment site.

Modifications made to the AIR-FLOW handy PERIO Dental Handpiece to produce the AIR-FLOW handy 3.0 PERIO were limited to minor design changes to enhance

the ergonomics of the design, including:

- Location of the powder chamber is modified to improve the visibility of the mouth of the patient by the practitioner during the treatment
- Slimmer shape of the powder chamber to be in-line with the body of the device to improve the visibility of the mouth of the patient by the practitioner during the treatment.
- Diameter of the powder chamber cap is reduced to be in-line with new design of the powder chamber.
- The powder chamber capacity has been slightly decreased to 21g from 23g to fit new ergonomic design.
- The body of the AIR-FLOW handy 3.0 PERIO is made of 2 glued molded parts instead of 1 molded part
- The handpiece is shorter and slimmer to improve ergonomics.

Accessories were included to aid in filling the powder chamber and removing residual powder from the handpiece channels.

5. INTENDED USE

The AIR-FLOW handy 3.0 PERIO is intended for patients suffering from periodontal disease.

The AIR-FLOW handy 3.0 PERIO is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

The proposed AIR-FLOW handy 3.0 PERIO is similar in design and materials to the AIR-FLOW handy PERIO Dental Handpiece. Both the proposed AIR-FLOW handy 3.0 PERIO and the predicate AIR-FLOW handy PERIO connect to a standard turbine connection on a dental operative unit and consists of a hand-held device containing air and water lines, powder chamber with cap and an AIR-FLOW nozzle. The proposed and predicate handpieces deliver a mixture of water, air, and dental powder to a treatment site. Differences between the proposed and predicate handpieces were limited to design changes to improve the ergonomics of the handpiece design and ease of use.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Non-clinical performance testing of the modified handpiece included functional verification of the hardware modifications at the component and finished device level and user evaluations to validate the design improvements. The results confirmed that that the AIR-FLOW handy 3.0 PERIO fulfilled all prospectively defined performance specifications.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Clinical testing was not conducted.

9. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTING

The similarities in intended use, operational characteristics, and functional technological characteristics between the AIR-FLOW handy 3.0 PERIO and the AIR-FLOW handy PERIO lead to a conclusion of substantial equivalence between the proposed and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 24, 2014

E.M.S. Electro Medical Systems SA
C/O Cynthia J. M Nolte, Ph.D., RAC
Aptiv Solution
62 Forest Street, Suite 300
Marlborough, MA 01752

Re: K132480
Trade/Device Name: AIR-FLOW handy 3.0 PERIO
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories
Regulatory Class: I
Product Code: EFB
Dated: December 18, 2013
Received: December 19, 2013

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S FDA for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132480

Device Name: AIR-FLOW handy 3.0 PERIO

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Prescription Use _X_ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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